**Remarks/Arguments**

Entry of the present amendment and reconsideration of the above-identified application in view of the present amendment is respectfully requested. By the present amendment, claims 11, 15, and 22 have been amended. Claims 13, 23-29, and 31-32 have been canceled. The present amendment adds the limitations of claim 13 to claim 11, corrects the dependency of claims 15 and 22, and cancels claims. Thus, the present amendment does not introduce new matter or require further searching by the Examiner and the present amendment is believed to be appropriate.

Claims 11, 15-18, 20-29, 31 and 32 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,877,424 to Murray (hereafter "Murray"). Claims 23-29 and 31-32 have been canceled and, thus, the rejection of claims 23-29 and 31-32 is moot. It is respectfully submitted that amended claim 11 is patentable over Murray and is therefore allowable.

Anticipation requires a single prior art reference that discloses each element of the claim. W.L. Gore & Associates v. Garlock, Inc., 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), cert. denied 469 U.S. 851 (1984). Additionally, the single prior art reference must disclose each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention". Scripps Clinic & Research Foundation v. Genentech Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). "The identical invention

must be shown in as complete detail as is contained in the ... claim". Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Amended claim 11 recites that one or more one-piece fixation elements are adapted to be received in a bone structure and in a polyethylene chassis. The polyethylene chassis is made from UHMWPE which has an elasticity giving a locking effect by friction on the fixation elements in such a way that the fixation elements are frictionally engaged by the UHMWPE chassis and thereby locked by friction regarding movement in axial, rotational, and angular directions. Amended claim 11 incorporates the subject matter of claim 13 and, thus, the rejection of claim 13 is addressed.

Murray does not teach or suggest a chassis that has an elasticity giving a locking effect by friction on fixation elements in such a way that the fixation elements are frictionally engaged by the chassis and thereby locked by friction regarding movement in axial, rotational, and angular directions. Murray teaches a method and apparatus for the external fixation of bone fractures using a device that includes pins 13-16 and a polyethylene bladder 18 to be filled with fortified epoxy resin to fix the pins to the bladder. The pins 13-16 must be held in place using a temporary bridge while the epoxy resin in the bladder 18 is hardened using an injected hardener or catalyst (Col. 1 lines 26-65). More specifically, the pins 13-16 are clamped between clamp plates 21a, 21b, 22a, 22b of the temporary bridge and held in position during the time the bladder is filled with unhardened cement is placed over the exposed ends of the pins and hardened (Col. 2, lines 52-56 and Fig. 9). In

fact, the bladder 18 can be removed as desired from the pins 13-16 at any time prior to hardening (Col. 2, lines 42-43).

In other words, before the epoxy resin within the bladder 18 hardens, the bladder is incapable of preventing movement of the pins 13-16 – otherwise the temporary bridge would be redundant and unnecessary. In fact, the temporary bridge has a mechanism for adjusting the position of the pins 13-16 relative to the bridge before the resin is hardened to improve the position of the bone and bone fragments (Col. 1, lines 61-65). Even when the bladder 18 becomes secured to the pins 13-16, the attachment between the bladder 18 and the pins is due to adhesion – not friction. In particular, when the hardening agent is injected into the bladder 18, the epoxy resin hardens and adheres to the outer surfaces of the pins 13-16 in order to secure the bladder to the pins. If the hardened epoxy resin did not adhere to the pins 13-16 the resin would simply harden around the pins and allow the bladder 18 to slide along the pins – a clearly undesirable result. In other words, there is no frictional engagement between the hardened epoxy resin and the pins 13-16 in order to prevent movement of the pins. Accordingly, Murray does not teach or suggest a chassis that has an elasticity giving a locking effect by friction on fixation elements in such a way that the fixation elements are frictionally engaged by the chassis and thereby locked by friction regarding movement in axial, rotational, and angular directions, as recited in amended claim 11.

Furthermore, the Examiner acknowledges that Murray does not teach or suggest a chassis made of UHMWPE, but asserts that it would have been an obvious matter of design choice to form the bladder 18 of Murray out of UHMWPE

on the basis of its suitability for the intended use (Office Action page 3). If the bladder 18 of Murray was made from UHMWPE, however, the bladder would be rendered unsuitable for its intended purpose.

In considering the question of *prima facie* obviousness, the Federal Circuit has consistently held that when a rejection under 35 U.S.C. §103 is based upon a modification of a reference that destroys the intent, purpose, or function of the invention disclosed in the reference, such a proposed modification is not proper and the *prima facie* case of obviousness cannot be properly made. See, *In re Gordon,* 733 F.2d 900, 221 USPQ1125 (Fed. Cir. 1984). Also, it is improper to combine references where the references teach away from their combination. *In re Grasselli,* 713 F.2d 791, 743, 218 USPQ 769, 779 (Fed. Cir. 1983); See also, MPEP §2145 X.D.2. Further, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Murray teaches that the bladder 18 is formed from pliable polyethylene (Col. 2, lines 34-35). The pliability of the bladder 18 allows the pins 13-16 to be pushed through the bladder and into the fractured bone while allowing the epoxy resin within the bladder to move and accommodate various pin configurations and positions before hardening. Therefore, modifying the pliable polyethylene bladder 18 of Murray to be formed of UHMWPE would not be obvious to one having ordinary skill because UHMWPE is not a pliable material as defined in Murray.

In particular, as evidenced by the attached Appendix A, compared to low density polyethylene (LDPE), UHMWPE is harder, stronger, and has a lower tensile elongation, i.e., is more brittle, than LDPE. In other words, UHMWPE is too brittle and hard to be formed into a pliable bladder 18 through which pins 1-316 are pushed and which can conform to a variety of pin configurations and orientations to ensure proper fracture healing. Examination of the typical uses for UHMWPE, e.g., hip, knee, and shoulder replacements, confirm that it is intended to be used for high strength applications requiring improved wear characteristics, high impact strength, and toughness – not as a pliable bladder 18 that receives epoxy resin as suggested by the Examiner. For these reasons, one having ordinary skill would not replace the pliable polyethylene bladder 18 in Murray with a bladder formed from UHMWPE as such a modification renders the bladder unsuitable for its intended purpose.

Moreover, the use of UHMWPE for the chassis of the present invention provides a number of specific advantages over the prior art, e.g., no temporary bridge or additional steps such as mixing, pouring, and hardening the epoxy resin are needed. More specifically, using the UHMWPE chassis of the present invention allows the surgeon to be free to place the screws optimally during operation without the need to further support the screws because once the screws are positioned within the UHMWPE chassis, the material gives a frictional force on the screws that prevents them from coming out. Furthermore, the bending rigidity of UHMWPE is sufficient to allow the fracture to heal and eliminate the risk of braking. On the other hand, using the bladder 18 of Murray with fortified epoxy does not provide the same advantages. Therefore, the choice of material for the chassis of the present

contributes to the new improved system for fixation with the previously mentioned advantages. Based on the foregoing, it is respectfully submitted that amended claim 11 is patentable over Murray and is therefore allowable.

Claims 15-18 and 20-22 depend from claim 11 and are allowable for at least the same reasons as claim 11 and for the specific limitations recited therein.

Furthermore, amended claim 15 recites that the screws of the fixation elements are screwed into the chassis and bone structure in such a way that the screws move equidistantly in the chassis and the bone structure. Murray does not teach or suggest this structure. In Murray, the bladder 18 is pushed over the pins 13-16 after the pins have been driven percutaneously into the fractured bone (Col. 2, lines 30-40). Since the pins 13-16 are already secured within the bone when the bladder 18 is attached thereto, the pins cannot be screwed into the bladder. Therefore, Murray does not teach or suggest the structure recited in amended claim 15. Accordingly, it is respectfully submitted that amended claim 15 is patentable over Murray and is therefore allowable.

Claim 18 recites that the chassis is received in a rigid bracing. The Examiner asserts that the epoxy resin in Murray constitute the rigid bracing of the present invention. The epoxy resin, however, is held within the bladder 18 and, thus, the bladder cannot be received within the resin. Therefore, Murray does not teach or suggest the structure recited in claim 18. Accordingly, it is respectfully submitted that claim 18 is patentable over Murray and is therefore allowable.

Claims 13 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Murray. Claim 13 has been canceled and, thus, the rejection of

claim 13 is moot. Claim 19 depends from claim 11 and is allowable for at least the same reasons as claim 11 and for the specific limitations recited therein.

In view of the foregoing, it is respectfully submitted that the above-identified application is in condition for allowance, and allowance of the above-identified application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,

**/James L. Tarolli/**
James L. Tarolli
Reg. No. 36,029

TAROLLI, SUNDHEIM, COVELL,
& TUMMINO L.L.P.
1300 East Ninth Street, Suite 1700
Cleveland, Ohio 44114-1400
Phone:(216) 621-2234
Fax: (216) 621-4072
Customer No.: 26,294

# APPENDIX A

Boedeker.com

# Polyethylene Specifications

**904 West 6th Street, Shiner, Texas 77984 USA**
**Phone: 1-361-594-2941 Fax: 1-361-594-2349 E-Mail: bpi@boedeker.com**

## 1-800-444-3485

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## GENERAL DESCRIPTION

Polyethylenes are semi-crystalline materials with excellent chemical resistance, good fatigue and wear resistance, and a wide range of properties (due to differences in length of the polymer chain.) Polyethylenes are easy to distinguish from other plastics because they float in water.

## GENERAL PROPERTIES OF POLYETHYLENES

Polyethylenes provide good resistance to organic solvents, degreasing agents and electrolytic attack. They have a higher impact strength, but lower working temperatures and tensile strengths than polypropylene. They are light in weight, resistant to staining, and have low moisture absorption rates.

## POLYETHYLENE GRADES

### Low Density Polyethylene (LDPE)

This extruded material offers good corrosion resistance and low moisture permeability. It can be used in applications where corrosion resistance is important, but stiffness, high temperatures, and structural strength are not. A highly flexible product, LDPE is used widely in orthopaedic products, or where mobility without stress fatigue is desired. LDPE is also frequently used in comsumer packaging, bags, bottles, and liners.

### High Density Polyethylene (HDPE)

Representing the largest portion of the polyethylene applications, HDPE offers excellent impact resistance, light weight, low moisture absorption, and high tensile strength. HDPE is also non-toxic and non-staining and meets FDA and USDA certification for food processing.

### Ultra High Molecular Weight Polyethylene (UHMW PE)

Light weight (1/8 the weight of mild steel), high in tensile strength, and as simple to machine as wood, UHMW PE is the ideal material for many wear parts in machinery and equipment as well as a superb lining in material handling systems and storage containers. UHMW PE is self-lubricating, shatter resistant, long-wearing, abrasion and corrosion resistant. It meets FDA and USDA acceptance for food and pharmaceutical equipment and is a good performer in applications up to 180 °F (82 °C) or when periodically cleaned with

live steam or boiling water to sterilize.

( see also Lennite® Conductive and Tivar® 1000 AntiStatic UHMW Specifications )
( see also QuickSilver® Liners )

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## TYPICAL PROPERTIES of POLYETHYLENE

| ASTM or UL test | Property | LDPE | HDPE | UHMW |
|---|---|---|---|---|
| | ***PHYSICAL*** | | | |
| D792 | Density (lb/in³)<br>(g/cm³) | 0.033<br>0.92 | 0.035<br>0.95 | 0.034<br>0.93 |
| D570 | Water Absorption, 24 hrs (%) | <0.01 | 0 | 0 |
| | ***MECHANICAL*** | | | |
| D638 | Tensile Strength (psi) | 1,800-2,200 | 4,600 | 3,100 |
| D638 | Tensile Modulus (psi) | - | - | 125,000 |
| D638 | Tensile Elongation at Yield (%) | 600 | 900 | - |
| D790 | Flexural Strength (psi) | - | - | - |
| D790 | Flexural Modulus (psi) | - | 200,000 | 125,000 |
| D695 | Compressive Strength (psi) | - | - | 2,000 |
| D695 | Compressive Modulus (psi) | - | - | - |
| D785 | Hardness, Shore D | D41-D50 | D69 | D62-D66 |
| D256 | IZOD Notched Impact (ft-lb/in) | No Break | 3 | No Break |
| | ***THERMAL*** | | | |
| D696 | Coefficient of Linear Thermal Expansion<br>(x $10^{-5}$ in./in./°F) | 3 | 6 | 11 |
| D648 | Heat Deflection Temp (°F / °C)<br>at 66 psi<br>at 264 psi | 120 / 48<br>105 / 36 | 170 / 76<br>150 / 40 | 203 / 95<br>180 / 82 |
| D3418 | Approx. Melting Temperature (°F / °C) | 230 / 110 | 260 / 125 | 280 / 138 |
| - | Max Operating Temp (°F / °C) | 160 / 71 | 180 / 82 | 180 / 82 |
| C177 | Thermal Conductivity<br>(BTU-in/ft²-hr-°F)<br>(x $10^{-4}$ cal/cm-sec-°C) | -<br>- | -<br>- | 2.92<br>10.06 |
| UL94 | Flammability Rating | n.r. | n.r. | H-B |
| | ***ELECTRICAL*** | | | |
| D149 | Dielectric Strength (V/mil) short time, 1/8" thick | 460-700 | 450-500 | 900 |
| D150 | Dielectric Constant at 1 kHz | 2.25-2.30 | 2.30-2.35 | 2.30-2.35 |
| D150 | Dissipation Factor at 1 kHz | 0.0002 | 0.0002 | 0.0002 |
| D257 | Volume Resistivity (ohm-cm) at 50% RH | $10^{15}$ | $10^{15}$ | $10^{18}$ |
| D495 | Arc Resistance (sec) | 135-160 | 200-250 | 250-350 |

NOTE: The information contained herein are typical values intended for reference and comparison purposes only. They should NOT be used as a basis for design specifications or quality control. Contact us for manufacturers' complete material property datasheets.
All values at 73°F (23°C) unless otherwise noted.

**Boedeker Plastics, Inc.**
904 West 6th Street, Shiner, Texas 77984 USA
**USA TOLLFREE : 1-800-444-3485**
Phone: 1-361-594-2941 Fax: 1-361-594-2349 E-Mail: bpi@boedeker.com